STATE OF NEW MEXICO
FIRST JUDICIAL DISTRICT
COUNTY OF SANTA FE

No. D101CV2006 02090

STATE OF NEW MEXICO, ex rel.,
PATRICIA MADRID, ATTORNEY GENERAL
OF THE STATE OF NEW MEXICO,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

COMPLAINT
FOR DECLARATORY RELIEF, DAMAGES & RESTITUTION

The People of the State of New Mexico, by their attorney, Patricia Madrid, Attorney General of the State of New Mexico, allege the following upon information and belief:

1. Plaintiff is the State of New Mexico on the relation of its Attorney General, Patricia Madrid. Plaintiff is acting pursuant to her authority under, inter alia, Section 8-5-2 NMSA 1978, and the New Mexico Unfair Practices Act, §§57-12-2 et seq., NMSA 1978 (1995 Repl.). Plaintiff brings this action to obtain declaratory and equitable relief, damages and restitution. Plaintiff seeks to recover the costs of Olanzapine (ZYPREXA®)-induced diabetes and diabetes-related illnesses to the State of New Mexico, including, but not limited to, increased expenditures for:

a. Medical assistance provided under New Mexico's Medicaid program pursuant to the Public Assistance Act, §§27-2-12 et seq. NMSA 1978 (1995

Repl. and 1996 Supp.). Under the medical assistance program, the State of New Mexico pays for medical services provided to program recipients. The State pays approximately 25% of these costs, with the federal government bearing the remaining costs.

b. Public employees' health and disability insurance coverage costs pursuant to the Group Benefits Act, §10-7B-6 NMSA 1978 (1995 Repl.).

c. Public employees' disability retirement pension costs pursuant to the Public Employees Retirement Act, §10-11-10.1 NMSA 1978 (1995 Repl.).

d. Retired public employees' group health insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, §10-7C-8 NMSA 1978 (1995 Repl.).

e. Public school employees and school board retirees' group health insurance costs from the Public School Insurance Fund, pursuant to the Public School Insurance Act, §22-2-6.6 NMSA 1978 (1993 Repl.), and disability benefits from the Educational Retirement Fund, pursuant to the Educational Retirement Act, §§22-11-1 et seq., NMSA 1978 (1993 Repl.).

2. In fulfilling its statutory duties, the State of New Mexico has expended and will expend substantial sums of money due to the increased costs of providing health care services for Olanzapine (ZYPREXA®)-induced diabetes and diabetes-related illnesses.

THE PARTIES

3. The Plaintiff, the State of New Mexico, by and through Patricia Madrid, the duly elected and current Attorney General, brings this action in its sovereign capacity on behalf of its natural citizens and public agencies of the State. The Attorney General is acting pursuant to her authority under, inter alia, Section 8-5-2, NMSA 1978 and the New Mexico Unfair Practices Act, §§57-12-2 et seq., NMSA 1978 (1995 Repl.).

4. Defendant, ELI LILLY AND COMPANY ("Eli Lilly"), is a corporation organized under the laws of the state of Indiana with headquarters in Indianapolis, Indiana, authorized to and doing business in the State of New Mexico. Defendant ELI LILLY designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as ZYPREXA® (also known as OLANZAPINE).

5. At all times herein mentioned, Eli Lilly acted by itself, or by and through agents and employees, in doing the acts alleged herein, and at all times, said agents and employees were acting within the purpose and scope of said agency and employment, and all said acts were ratified and approved by Eli Lilly.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to, inter alia, Article VI, Section 13 of the New Mexico Constitution.

7. Venue is proper in Santa Fe County pursuant to Section 38-3-1 NMSA 1978. The Attorney General resides in Santa Fe County.

FACTUAL BACKGROUND

8. Olanzapine, brand name ZYPREXA®, is a prescription pharmaceutical manufactured by Eli Lilly, which is sold in all states, including New Mexico.

9. ZYPREXA® was approved for commercial sale in the United States, including the state of New Mexico, in 1996.

10. ZYPREXA® is among a group of drugs called the "atypical antipsychotic drugs" prescribed for the treatment of schizophrenia and bipolar mania.

11. ZYPREXA® has been widely advertised by the ELI LILLY as effective treatment for bipolar disorder and schizophrenia, with fewer adverse side effects than other treatments. Although ZYPREXA® was only approved by the Food and Drug Administration ("FDA") to treat schizophrenia and bipolar mania, ELI LILLY also induced physicians to prescribe ZYPREXA® off-label for treating other illnesses. Off-label use is the practice of prescribing drugs for a purpose outside the scope of the drug's approved label. ELI LILLY promoted ZYPREXA® for numerous off-label conditions, including depression, anxiety, dementia, Alzheimer's disease, Attention Deficit Disorder ("ADD"), Attention Deficit Hyperactivity Disorder ("ADHD"), sleep disorders, eating disorders, anger management, mood enhancement or mood stabilizers.

12. Zyprexa® is the most expensive, largest selling atypical antipsychotic in the world and the most widely prescribed antipsychotic of any kind in the United States.

Zyprexa®'s 2004 United States sales were $2.4 billion. United States sales for 2005 were $2 billion.

13. New Mexico's Medicaid program has paid at least $18 million for ZYPREXA® from 1999 through September of 2005.

14. ELI LILLY, beginning in 1996, aggressively marketed and sold ZYPREXA® by falsely misleading potential users about the products and by failing to protect users from serious dangers which ELI LILLY knew or should have known to result from use of ZYPREXA®.

15. At least as early as 1998, the medical literature conclusively revealed data which linked ZYPREXA® with causing diabetes. An indicative report was published on October 15, 1998 in the Society of Biological Psychiatry, Volume 44, Number 8, pages 778-83, titled "Novel Antipsychotics and New Onset Diabetes." Other numerous reports and studies are prevalent throughout the medical literature from 1998 through the present which detail a causal link between the ingestion of ZYPREXA® and the development of hyperglycemia, diabetes and ketoacidosis, as well as many other undisclosed risks. On July 1, 2002, Duke University Medical Center issued a Press Release about the recent finding that linked ZYPREXA® to early onset diabetes. The researchers identified 289 cases of diabetes in patients who had been prescribed ZYPREXA®. These findings were published on July 2, 2002 in the medical journal Pharmacotherapy, Vol. 22, No. 7, pages 841-52. The known danger ZYPREXA® was causing hyperglycemia and diabetes was never indicated by ELI LILLY to physicians

who prescribed the product to consumers or the State of New Mexico.

16. On, or shortly after September 15, 2003, ELI LILLY changed the warnings section of ZYPREXA®'s Package Insert, which contains full prescribing information for the drug, to include the risk of developing hyperglycemia from ingesting the drug. The revised Package Insert states:

> Hyperglycemia and Diabetes Mellitus -- Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases hyperglycemia has resolved with the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of suspect drug.

17. Eli Lilly sent a Dear Health Care Provider (hereinafter "DHCP Letter ") to hundreds of thousands of healthcare providers, including healthcare providers in New Mexico, dated March 1, 2004, indicating the Warnings section change to the Zyprexa® Package Insert, but only in the context of a "class" labeling change, and offering no other explanation for the change.

18. At all times before the DHCP letter was mailed, including but not limited to the time between the date when the Zyprexa® label was supposed to be changed and the date when DHCP letter was mailed:

a. Eli Lilly's sales representatives made personal contacts with physicians and other health care professionals in New Mexico, by visiting their offices in this state and by other means, and they orally made willfully misleading and deceptive statements regarding the safety and efficacy of Zyprexa®.

b. Eli Lilly's sales representatives persistently and willfully disparaged competitors' products by falsely and misleadingly misrepresenting to physicians and other health care professionals in New Mexico that Zyprexa® had been shown to have an efficacy, safety and overall risk-benefit profile superior to other drugs in its class.

c. Eli Lilly distributed Zyprexa® promotional brochures, containing essentially the same willfully deceptive and misleading information above, to physicians and other health care professionals in New Mexico.

d. Eli Lilly ran advertisements for Zyprexa® in medical professional journals and in other magazines with medical professionals as their target audience, which were mailed by their publishers to physicians and other health care professionals in New Mexico; and these advertisements deceptively perpetuated the understatement of risk and overstatement of benefit detailed above.

e. Eli Lilly otherwise willfully, deceptively, and misleadingly misrepresented Zyprexa®'s risk-benefit profile to health care professionals in New Mexico.

f. Eli Lilly specifically promoted Zyprexa® to physicians, including but not limited to primary care physicians in New Mexico, for non-approved indications such as symptoms of anxiety, irritability. Disruptive sleep, and mood swings.

g. Eli Lilly specifically promoted Zyprexa® to physicians, including but not limited to primary care physicians in New Mexico, for non-approved indications for use in treating the elderly, including dementia and Alzheimer's disease, even though Zyprexa® was never approved for such uses.

h. Eli Lilly specifically promoted Zyprexa® to physicians, including but not limited to primary care physicians in New Mexico, for use in children, including treatment for Attention Deficit Hyperactivity Disorder ("ADHD") and Attention Deficit Disorder ("ADD"), even though Zyprexa® was never approved for treatment in children or for treating these disorders.

19. At all times prior to the DHCP Letter, Eli Lilly knew, or should have known, that Zyprexa® was extremely and unreasonably unsafe for use by the general public. The dangers of Zyprexa®, including, by way of example, the increased likelihood of developing hyperglycemia, diabetes, ketoacidosis, pancreatitis, hyperosmolar coma and other injuries. Eli Lilly knowingly, willfully and maliciously failed to take appropriate action to either cure the nature of these defects or to warn users of the product or physicians of such dangerous characteristics.

VIOLATIONS OF THE NEW MEXICO UNFAIR PRACTICES ACT [Section 57-12-2 NMSA 1978]

The State re-alleges the preceding paragraphs of this Complaint.

20. Eli Lilly engaged in a course of repeated and willful conduct, through the acts and omissions described above.

21. Eli Lilly's willful and repeated acts and omissions relating to Zyprexa®, as described above, constitute unfair methods of competition, and they constitute unfair or deceptive acts or practices in the conduct of commerce, both of which violate the New Mexico Unfair Practices Act, Section 57-12-2 NMSA 1978.

a. Eli Lilly represented to health care professionals in New Mexico that Zyprexa® has characteristics, uses and benefits that it does not have in violation of Section 57-12-2 (D)(5) NMSA 1978.

b. Eli Lilly represented to health care professionals in New Mexico that Zyprexa® has benefits as compared to other atypical antipsychotics that it does not have in violation of Section 57-12-2 (D)(7) NMSA 1978.

c. Eli Lilly represented to health care professionals in New Mexico that Zyprexa® has fewer risks and side effects as compared to other atypical antipsychotics that it does not have in violation of Section 57-12-2 (D)(7) NMSA 1978.

d. Eli Lilly disparaged competitors and competitors' drugs to health care professionals in New Mexico by making false and misleading misrepresentations

of fact as to the risk-benefit profile of Zyprexa® relative to other atypical antipsychotics in violation of Section 57-12-2 (D)(8) NMSA 1978.

e. Eli Lilly engaged in conduct using exaggeration, innuendo or ambiguity as to material facts regarding the risk-benefit profile of Zyprexa® to health care professionals in New Mexico which created a likelihood of confusion and misunderstanding in violation of Section 57-12-2 (D)(14) NMSA 1978.

f. Eli Lilly made deceptive misrepresentations of material facts regarding Zyprexa® with the intention of having health care professionals in New Mexico rely on them in violation of Section 57-12-2 (D)(14) NMSA 1978.

g. Eli Lilly promotional activities regarding Zyprexa® including publishing and distributing statements to health care professionals in New Mexico which were misleading and deceptive, and which omitted material information necessary to make the statements not be misleading and deceptive in violation of Section 57-12-2 (D)(14) NMSA 1978.

h. Eli Lilly specifically promoted Zyprexa® for non-approved and non-indicated uses, including depression, anxiety, dementia, Alzheimer's disease, Attention Deficit Disorder ("ADD"), Attention Deficit Hyperactivity Disorder ("ADHD"), sleep disorders, eating disorders, anger management, mood enhancement or mood stabilizers in violation of Section 57-12-2 (D)(2) NMSA 1978, Section 57-12-2 (D)(5) NMSA 1978, and Section 57-12-2 (D)(14) NMSA 1978.

i. Eli Lilly's conduct constitutes an unconscionable trade practice in that it took advantage of the lack of knowledge of the New Mexico health care professionals regarding Zyprexa®'s risk-benefit profile in violation of Section 57-12-2 (E)(1) NMSA 1978.

j. Eli Lilly's conduct constitutes an unconscionable trade practice in that it resulted in a gross disparity between the value received by the New Mexico residents and the price paid, in violation of Section 57-12-2 (E)(2) NMSA 1978.

22. Each exposure of a New Mexico health care professional to misleading and deceptive information regarding Zyprexa® communicated in any manner by a sales representative constitutes a separate violation pursuant to Section 57-12-11 NMSA 1978.

23. Each exposure of a New Mexico health care professional to a misleading and/or deceptive print advertisement regarding Zyprexa® constitutes a separate violation pursuant to Section 57-12-11 NMSA 1978.

24. Each exposure of a New Mexico health care professional to a misleading and/or deceptive brochure regarding Zyprexa® constitutes a separate violation pursuant to Section 57-12-11 NMSA 1978.

25. Each exposure of a New Mexico health care professional to other misleading and/or deceptive information regarding Zyprexa®, provided directly or indirectly by Eli Lilly, e.g., by means of CD-ROM's, DVD's, dinners sponsored by Eli Lilly, PowerPoint presentations, promotional items, continuing medical education

materials and events sponsored by Eli Lilly and meeting sponsored by Eli Lilly, constitutes a separate violation pursuant to Section 57-12-11 NMSA 1978.

26. Each exposure of a New Mexico resident to Zyprexa® resulting from aforementioned conduct of Eli Lilly constitutes a separate violation pursuant to Section 57-12-11 NMSA 1978.

27. Eli Lilly's violations of the Unfair Practices Act were and continue to be willful.

28. Unless enjoined from doing so, Eli Lilly will continue to violate the New Mexico Unfair Practices Act.

29. As a direct and proximate result of Eli Lilly's wrongful conduct, the State of New Mexico has suffered and will continue to suffer substantial damage and injury.

VIOLATION OF NEW MEXICO MEDICAID PROGRAM
(Fraud and Abuse in the NM Medicaid Program)

30. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

31. Eli Lilly willfully made false representations of the safety of Zyprex® and the side effects caused by Zyprexa® which misled providers in the State of New Mexico, resulting in the sales of Zyprexa® which benefited Eli Lilly at the expense of the State of New Mexico Medicaid program.

32. Eli Lilly engaged in a fraudulent scheme which allowed providers to obtain payments from Medicaid based upon sales of Zyprexa® that would not have occurred if

Eli Lilly had disclosed to medical providers, the State and the public the risks of developing diabetes and other diseases from the use of Zyprexa®.

33. Eli Lilly knows the State relies on Eli Lilly and other drug manufacturers to design, market and sell prescription drugs that are effective and safe for use by the State's Medicaid program recipients.

34. Eli Lilly marketed Zyprexa® as safe and effective with the intent that the State, medical providers and the general public rely on its representations so that the medical providers would not prescribe, and the State pay for, other effective, safe prescription drugs for treatment of schizophrenia and bipolar disorder.

35. Some of the alternative drugs that could have been prescribed by medical providers, and paid for by the State cost significantly less than Zyprexa®, thereby causing the State to pay far more for Eli Lilly's Zyprexa® than it would have for equally effective, safer alternative drugs for the same treatment.

36. Eli Lilly benefited from its misrepresentations and fraudulent conduct by gaining sales of Zyprexa® at the expense of other, safe, effective drugs. The money paid by the State would not have been paid to Eli Lilly except for its fraudulent conduct.

37. Eli Lilly further benefited from its misrepresentations and fraudulent conduct by gaining sales of Zyprexa® for treatment of medical conditions not specifically approved by the FDA.

38. The State is entitled to three times the amount of the overpayments, reasonable attorney fees and all other fees and costs of litigation.

FRAUDULENT MISREPRESENTATION

39. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

40. Eli Lilly materially misrepresented the safety and uses of Zyprexa® to New Mexico, medical providers and the citizens of New Mexico.

41. Eli Lilly knew that the material representations were false when made and Eli Lilly intended that the representations would be relied upon by the State of New Mexico and its agencies. The State reasonably relied upon the material misrepresentations when determining to pay for Zyprexa®.

42. Eli Lilly had sole access to material facts regarding the off-label uses and the safety of Zyprexa®, yet affirmatively concealed the material facts from the State and its agencies, medical providers and the public.

43. Eli Lilly's acts constitute fraudulent misrepresentations. As a direct and proximate cause of Eli Lilly's fraudulent misrepresentations, the State and its agencies have been damaged and have spent money for these drugs that they otherwise would not have incurred had Eli Lilly not misrepresented the safety and uses of Zyprexa®.

RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of New Mexico, prays for judgment against Eli Lilly as follows:

A. Adjudge and decree that Eli Lilly engaged in conduct in violation of the New Mexico Unfair Practices Act, §§57-12-2 et seq., NMSA 1978;

B. Permanent injunctive relief and restitution against Eli Lilly pursuant to §57-12-8 (B) NMSA 1978;

C. Grant judgment in favor of the State and against Eli Lilly all equitable relief. Disgorgement, restitution and reimbursement, and require Eli Lilly to create a fund for the payment of future medical care that will be paid by the State and the public for injuries caused by Eli Lilly's conduct;

D. Award maximum civil penalties as provided by law;

E. Grant the State the costs of prosecuting this action, together with interest, including prejudgment interest, and reasonable attorneys' fees in connection with the prosecution of this case; and

F. Grant such further relief as this Court may deem just and proper under the circumstances.

Respectfully submitted,

PATRICIA A. MADRID
Attorney General of New Mexico

By _____
Glenn R. Smith
Deputy Attorney General
David K. Thomson

Assistant Attorney General

Bill Robins
300 Paseo de Peralta
Santa Fe, NM 87501

Rachel Adams
Mark Burton
Hersh & Hersh
601 Van Ness Ave., Suite 2080
San Francisco, CA 94102

ATTORNEYS FOR PLAINTIFF